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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/840,060	DEAK ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-8,11-17,19-21,24 and 26-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,18,22,23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicants' election with traverse of Group VIII, claims 9-18, 22, 23 and 25 in response to office action dated December 16, 2005, filed on February 21 2006 is acknowledged. Further Applicants have elected polynucleotide sequence SEQ ID NO: 142 encoding KIF-2 homologue with traverse.

The traversal is on the grounds that the restriction to one sequence is contrary to the guidelines set forth in MPEP 803.04 which permits the examination of a reasonable number of sequences in biotechnology cases, and that "normally ten (emphasis added) sequences constitute a reasonable number for examination purposes". Applicants further submit, that three additional sequences of claim 16 especially SEQ ID NOs: 144, 146 and 148 of Example 9, which are all directed to polynucleotide sequences in which mutations result in male sterility, should be included in the examination. Applicants submit that these sequences in Example 9 are similar to the elected sequence SEQ ID NO: 142 of Example 19. This argument has been considered but is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions, which are independent or distinct. Here, the inventions of the various sequences were clearly delineated in the restriction requirement including their distinctions and search burden. Further, MPEP 803.04 states that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. The MPEP does not include allegations of functional similarities as reason to combine multiple distinct chemical compounds. Further, as to the question of burden of search, functional similarities among distinct sequences would not alleviate the search burden because each sequence comprises a wide range of different nucleic acids and different lengths that would still require different searches in the large number of sequence databases, and there is no evidence that the searches would overlap. Further, different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

New claims 35 and 36 have been added. Of the pending claims 1-36, claims 1-8, 19-21, 24 and 26-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Please note that claims 11-17, 35, 36 are also withdrawn from further consideration as being drawn to a non-elected invention, because an election of SEQ ID NO: 142 of Example 19 has been made. Therefore, claims 9, 10, 18, 22, 23 and 25 are currently under consideration.

Objection to Specification

1). The specification is objected to because the continuing data on page 1, line 1 has not been updated. A correction is required.

2). The specification is objected to for improper disclosure of a multitude of amino acid and or nucleic acid sequences without a respective sequence identifier, i.e. a SEQ ID NO. For example, Figures 2 and 3 include sequence disclosures and the brief description of said figures does not include respective SEQ ID NOs:. Further, it appears that all of the sequence disclosures throughout the examples in the specification (i.e., Examples 1-29) lack respective sequence identifiers. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. ln the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

Objection to Claims

1). Claims 11-17, 35 and 36 are objected to for reference to nonelected subject matter and or non-elected claims. For example, Claims 11-17, 35 and 36 include sequences set forth in Examples 1 to 18, 20-29, however, only the sequence set forth in Example 19 is elected. Claim 13 refers to non-elected sequences listed in Table 5.

2). Claims 9, 10, 18, 22, 23 and 25 are objected to because the sequence in the claim is not identified by a SEQ ID NO.
A correction is required.

Claim Rejections – 35 USC § 101, Non-statutory

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9, 18 and dependent claim 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 9 and 18 recite "A polynucleotide" which reads on the naturally occurring polynucleotides. The rejection would be obviated by the insertion of language indicating that the polynucleotide was "isolated" or "purified".

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 10, 18, 22, 23 and 25 are rejected under 35 U.S.C. 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth an isolated polynucleotide comprising the nucleic acid sequence set forth in Example 19 (SEQ ID NO: X) and or the complete complement thereof and therefore the written description is not commensurate in scope with the claims which read on various unrelated polynucleotides that may have some sequences in common with the polynucleotide set forth in

Example 19. The claims are broadly drawn to polynucleotides comprising any ONE of the nucleotide sequence in Example 19, a polynucleotide comprising a nucleotide sequence capable of hybridizing to the nucleotide sequence set forth in Example 19 or a fragment thereof, a polynucleotide capable of hybridizing to the complement of the nucleotide sequence set forth in Example 19, a polynucleotide comprising a polynucleotide sequence which is degenerate as a result of the genetic code to the later claimed polynucleotides, and a polynucleotide which comprises a fragment of at least 15 nucleotides of any one of the nucleotide sequences of Example 19. The claims do not require that the polynucleotide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case the specification provides examples of a multitude of polynucleotide sequences; however there is insufficient guidance or evidence to suggest a relationship between said polunucleotides compared to the genus of claimed polynucleotides. However, there is no identification of any particular portion of the genus that must be conserved nor is there evidence of possession of the genus. For example, the specification proposes that polynucleotides which are not 100% homologous to the sequences of the present invention but fall within the scope of the invention can be obtained in a number of ways including probing DNA libraries made from a range of individuals, for example individuals from different populations. In addition, the specification proposes that other viral/bacterial, or cellular homologues particularly cellular homologues found in mammalian cells (e.g. rat, mouse, bovine and primate cells), may be obtained and such homologues and fragments thereof in general will be capable of selectively hybridizing to the sequences shown in the examples. However, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention

and reference to a potential method of isolating it. The compound itself is required.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, only an isolated polynucleotide comprising the nucleic acid sequence set forth in Example I9 (SEQ ID NO: X) and or the complete complement thereof but not the full breadth of the claims meets the written description provision of 35 U.S.C 112, first paragraph.

Claim Rejections – 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9, 10, 18, 22, 23, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to a polynucleotide sequence set forth in specific examples. For example, the elected invention is to Example 19. Recitation of "Example 19" is indefinite in that the specification does not associate any ONE particular nucleic acid sequence with Example 19. For example, Example 19 of the specification (pages 178-191) displays multiple nucleic acid sequences in the absence of a specific sequence identifier. Moreover, although the election refers to the polynucleotide sequence of SEQ ID NO: 142 encoding KIF-2 homologue, nowhere in the specification or in the sequence listing at page 139 it has been disclosed that polynucleotide sequence of SEQ ID NO: 142 encodes KIF-2 homologue. The present invention relates to Drosophila Corkscrew (CG3954) gene identified in Example 19 as a cell cycle gene, which has sequence identity to human Shp2 Protein-tyrosine phosphatase, non-receptor type 11 (Genebank Accession NO: D13540), see page 9, 11, Table 5, 6, Example 19. However, it is well known in the art that accession numbers can be altered, deleted, amended, or revised over time by various inventors. Hence, one of ordinary skill in the art would be unable to discern the metes and

bounds of the claimed invention. Also, the use of laboratory designations, only, to identify a particular molecule renders the claims indfinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify the claimed polynucleotide by a sequence identifier, e.g., a SEQ ID NO.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 10, 18, 22, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Venter et al. (US 2005/0208558 A1, Publication date: September 22, 2005, Priority Date: October 19, 1999).

Due to the indefiniteness of the claims as set forth above, it is assumed for examination purposes that the claims encompass any polynucleotide that have commonality with the polynucleotide sequence set forth in SEQ ID NO: 142.

Venter et al. teach the primary nucleotide sequence of a large portion of the *Drosophila melanogaster* genome in a series of genomic or a representative fragment thereof and predicted transcript sequences. The fragments include fragments that encode peptides, the open reading frames (ORF), and fragments that modulates the expression of an operably linked ORF, the expression modulating fragments (EMF), see page 1, col. 2, paragraph [0010] and page 2, col. 1, paragraph [0013]. One of Venter's polynucleotide sequence has 100% sequence identity to SEQ ID NO: 142 of instant application (see sequence alignment result 2, Database: Published_Applications_NA_Main, US 11-097-143-1103). Thus, the prior art inherently teaches a polynucleotide selected from: a) a polynucleotide comprising at least one of the nucleotide sequences set forth in Example 19 or a complement thereof, or b) a polynucleotide comprising a nucleotide sequence that hybridizes to the nucleotide sequence set forth in Example 19 or a

fragment thereof, or c) a polynucleotide comprising a polynucleotide sequence which is degenerate as a result of the genetic code to the said sequences of polynucleotides in a) or b), thus anticipating claims 9 and 10 of instant application. Any fragment from Ventor's sequence which has 100% sequence identity is considered for a polynucleotide probe which comprises a fragment of at least 15 consecutive nucleotides of one of the nucleotides in Example 19 (claim 18), wherein said probe is considered for the probe used in the method for detecting the polynucleotide of claim 9 in a biological sample (claim 25). Furthermore Venter teaches the use of the fragments to generate a *Drosophila melanogaster* library by inserting them into plasmid vectors or lamda vectors (see page 5, col. 1, paragraph [0051]. Absent evidence to the contrary, the method involved in the generation of the library would inherently encompass the use of recombinant DNA technology for expression and analysis including the use of vectors and or expression vectors comprising the polynucleotides operably linked to regulatory sequences capable of directing expression in a host cell as the use of cloning vectors for recombinant expression in host cells is well known in the art (claims 22, 23). Thus, claims 9, 10, 18, 22, 23 and 25 of instant application are being anticipated by Venter et al.

Conclusion

No claims are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.
May 25, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER